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EXAMINER	
KUDLA, JOSEPH S	

ART UNIT	PAPER NUMBER
1611	

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10/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,104	CAI ET AL.	
	Examiner	Art Unit	
	JOSEPH S. KUDLA	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *19-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Foreword

1. Applicants' Amendment-After Non-Final Rejection and amended claim set, filed March 19, 2008, are acknowledged. With respect to Applicants' Arguments/Remarks in the correspondence, the arguments and request for reconsideration have been fully considered and found to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejection and objection are newly applied. They constitute the complete set presently applied to the instant specification. This office action is **FINAL**.

Instant claims 1, 12 and 13 have been amended. Note: The Examiner in the previous office action failed to withdraw instant claims 19, 21, 23 and 25 from consideration as being drawn to non-elected subject matter see 37 CFR 1.142(b). The claims withdrawn from consideration are 19-26.

Instant claims 1-18 are presented for examination on the merits as they read upon the elected subject matter.

Priority

2. This application is a 371 of PCT/US2003/010645 (filed April 7, 2003), which claims benefit of US Provisional Application No. 60/369,806 (filed April 5, 2002). Priority to April 5, 2002.

3. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional

application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Provisional Application No. 60/369,806, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, Application No. 60/369,806 makes no disclosure of chemical agents or biological agents within the filing.

In view of the fact that all instant claims have these limitations either within the independent claim or claims dependent thereof, instant claims 1-18 are given a priority date of April 7, 2003.

New Matter

4. The amendment filed March 19, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment to instant claim 1 introduces "the proviso that said radionuclide is not a measured dose of radiation for cancer therapy." Nowhere in Applicants' original disclosure is there a provision that the radiation could not be radiation for cancer therapy.

Applicant states on page 17, paragraph 37 that "These types of exposure (*i.e.*, from a bomb or spill cleanup) are distinguished (*i.e.*, separate or different) from exposure of patients to measured doses of radiation for therapeutic reasons." It is the Examiner's position that Applicant was conveying the fact that the non-therapeutic exposure would not be the controlled exposure of a therapeutic exposure. Separating or exemplifying the difference between the therapeutic vs. non-therapeutic exposure from radionuclides is quite different than the support needed to enable the provision proposed in the amendment of instant claim 1.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-11 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Weber et al. (WIPO Application Publication WO 01/27140** and cited by Applicant and in previous office action). The instant application claims a method of treating of ameliorating diseases or conditions caused by the exposure to radionuclides, biological agents and chemical agents wherein the agent, a caspase inhibitor, modulates cell death in response to such exposure. The instant application claims the cell death can occur in the skin, hair, bone marrow *inter alia*. The instant application claims the agent can be administered topically or orally with a pharmaceutically acceptable carrier. The instant application claims the exposure to radionuclides, biological agents and chemical agents can be intentional or unintentional and the caspase can be administered prior, during and after the exposure. The instant application claims specific radionuclides, biological agents and chemical agents that would cause cell death and be modified via the administration of a caspase inhibitor.

Weber et al. teach the use of a caspase inhibitor to treat or ameliorate bone marrow cell death in an animal via administering a caspase inhibitor (reference claim 1) resulting from the chemotherapy or radiation therapy. Weber et al. teach that when chemotherapeutic agents and/or radiation kill cancer cells, an unwanted side effect is the apoptotic death of rapidly dividing non-cancer cells, such as the cells of the gastrointestinal tract, skin, hair and bone marrow cells (page 11, lines 22-25). Weber et al. teach topical or oral administration (reference claim 2) or injection (reference claim 11) and a pharmaceutical composition with an acceptable carrier (reference claim 12). Weber et al. teach the intentional administration due to chemotherapy (reference claim 1). Weber et al. teach the administration of the caspase inhibitor prior, during or after the exposure event (reference claims 17-19). Weber et al. teach various caspase inhibitor compounds (reference claims 13-16) which includes the compound Cbz-Val-Asp-CH_2F (reference claim 14, line 3). Weber et al. teach that skin, hair cells, gastrointestinal tract *inter alia* can be protected via the administration of a caspase inhibitor (page 12, lines 1-3). Weber et al. teach the caspase inhibitor can be administered intraperitoneally (page 36, line 23).

Weber et al. does not teach a method of treating of ameliorating diseases or conditions caused by the exposure to radionuclides or that intentional or unintentional exposure could be treated or that caspase inhibitor could be used before, during or after an event to reduce cell death.

Regarding the recitation "a disease or condition caused by exposure to radionuclides," the prior art meets this limitation since the prior art discloses radiation therapy. Radiation therapy uses radionuclides.

Regarding the recitation of "the proviso that said radionuclide is not a measured dose of radiation for cancer therapy," one of ordinary skill in the art at the time of the invention would have known that the inherent property responsible for the "disease or condition caused by exposure to radionuclides" is the ionizing energy of the radionuclide. One of ordinary skill in the art at the time of the invention would have realized that this inherent property is the same inherent property that induces cell death when x-ray therapy is administered. Therefore, regardless of the source of the ionizing energy, whether it is a therapeutic or non-therapeutic exposure to a radionuclide, the caspase inhibitor as taught by Weber et al. will be effective in treating or ameliorating a disease or condition caused by the exposure to the ionizing energy. Therefore, instant claim 1 is rendered obvious.

It would have been obvious to one of ordinary skill in the art at the time of the invention that because it has been shown that the caspase inhibitor Cbz-Val-Asp-CH_2F is capable of treating or ameliorating bone marrow cell death resulting from exposure to the ionizing radiation associated with radiation therapy, the caspase inhibitor Cbz-Val-Asp-CH_2F would also be effective at treating or ameliorating bone marrow cell death of another form of ionizing radiation, such as the ionizing radiation emitted from the various radionuclides on instant claim 11. One of ordinary skill in the art at the time of the invention would have been motivated to utilized the caspase inhibitor due to the

similarity in ionization strength between the therapeutic and non-therapeutic administered radionuclides and one of ordinary skill in the art would have had a reasonable expectation of success based upon the prior art by Weber et al. Therefore, instant claims 10 and 11 are rendered obvious.

Because the cell death cells that were treated in Weber et al. were bone marrow cells, instant claim 2 is rendered obvious. Because the caspase inhibitor is applied topically, instant claim 3 is rendered obvious. Because intraperitoneal injection and use with an acceptable pharmaceutical carrier was taught by Weber et al., instant claims 4 and 5 are rendered obvious.It would have been obvious to one of ordinary skill in the art at the time of the invention that regardless of an intentional or unintentional exposure and regardless of the where the exposure occurred, the caspase inhibitor would treat or ameliorate bone marrow cell death in a subject, thus rendering instant claims 6-9 obvious.

Because Weber et al. teach the administration of the caspase inhibitor can occur prior, during or after exposure to the radiation event, instant claims 14-16 are rendered obvious. Because Weber et al. teach the same genus and elected species as Applicant for use in treating or ameliorating cell death, instant claims 17 and 18 are rendered obvious.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Weber et al. (WIPO Application Publication WO 01/27140** and cited by Applicant and in previous office action) in view of **Li et al. ("Oxidative stress and cyclooxygenase-2**

induction mediate cyanide induced apoptosis of cortical cells," 2001, Int. J. Oncol., Volume 18, Number 4, Abstract and cited by Applicant).

The instant application claims a method of treating of ameliorating diseases or conditions caused by the exposure to radionuclides, biological agents and chemical agents wherein the agent, a caspase inhibitor, modulates cell death in response to such exposure. The instant application claims the cell death can occur in the skin, hair, bone marrow *inter alia*. The instant application claims the agent can be administered topically or orally with a pharmaceutically acceptable carrier. The instant application claims the exposure to radionuclides, biological agents and chemical agents can be intentional or unintentional and the caspase can be administered prior, during and after the exposure. The instant application claims specific radionuclides, biological agents and chemical agents that would cause cell death and be modified via the administration of a caspase inhibitor.

Weber et al. teach the use of a caspase inhibitor to treat, ameliorate bone marrow cell death in an animal via administering a caspase inhibitor (reference claim 1) resulting from the chemotherapy or radiation therapy. Weber et al. teach that when chemotherapeutic agents and/or radiation kill cancer cells, an unwanted side effect is the apoptotic death of rapidly dividing non-cancer cells, such as the cells of the gastrointestinal tract, skin, hair and bone marrow cells (page 11, lines 22-25). Weber et al. teach topical or oral administration (reference claim 2) or injection (reference claim 11) and a pharmaceutical composition with an acceptable carrier (reference claim 12). Weber et al. teach the intentional administration due to chemotherapy (reference claim

1). Weber et al. teach the administration of the caspase inhibitor prior, during or after the exposure event (reference claims 17-19). Weber et al. teach various caspase inhibitor compounds (reference claims 13-16) which includes the compound Cbz-Val-Asp-CH_2F (reference claim 14, line 3). Weber et al. teach that skin, hair cells, gastrointestinal tract *inter alia* can be protected via the administration of a caspase inhibitor (page 12, lines 1-3). Weber et al. teach the caspase inhibitor can be administered intraperitoneal (page 36, line 23).

See 35 U.S.C. 103 rejection at 5 *supra* for the rejection of instant claims 1-11 and 14-18.

Weber et al. does not teach a method of treating of ameliorating diseases or conditions caused by the exposure to chemical agents such as cyanide.

Li et al. teach that the micromolar administration of potassium cyanide induced apoptosis in cortical cells (Abstract).

One of ordinary skill in the art at the time of the invention would have known that chemotherapeutic agents, as is the case with cyanide as taught by Li et al., is toxic to cells and causes apoptosis.

It would have been obvious to one of ordinary skill in the art at the time of the invention that because it has been shown that the caspase inhibitor Cbz-Val-Asp-CH_2F is capable of treating or ameliorating bone marrow cell death resulting from exposure to a toxic agent such as a chemotherapeutic agent, the caspase inhibitor Cbz-Val-Asp-CH_2F would also be effective at treating or ameliorating apoptosis of other cells subjected to a toxic agent such as cyanide. One of ordinary skill in the art at the time of

the invention would have been motivated to utilized the caspase inhibitor due to the similarity between the toxic effects of a chemotherapeutic agent and cyanide and one of ordinary skill in the art would have had a reasonable expectation of success based upon the prior art by Weber et al.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Weber et al. (WIPO Application Publication WO 01/27140** and cited by Applicant and in previous office action) in view of **Park et al. (" Macrophage apoptosis by anthrax lethal factor through p38 MAPK kinase inhibition," 2002, Science, Volume 297, Page 5589, Abstract** and cited by Applicant).

The instant application claims a method of treating of ameliorating diseases or conditions caused by the exposure to radionuclides, biological agents and chemical agents wherein the agent, a caspase inhibitor, modulates cell death in response to such exposure. The instant application claims the cell death can occur in the skin, hair, bone marrow *inter alia*. The instant application claims the agent can be administered topically or orally with a pharmaceutically acceptable carrier. The instant application claims the exposure to radionuclides, biological agents and chemical agents can be intentional or unintentional and the caspase can be administered prior, during and after the exposure. The instant application claims specific radionuclides, biological agents and chemical agents that would cause cell death and be modified via the administration of a caspase inhibitor.

Weber et al. teach the use of a caspase inhibitor to treat or ameliorate bone marrow cell death in an animal via administering a caspase inhibitor (reference claim 1) resulting from the chemotherapy or radiation therapy. Weber et al. teach that when chemotherapeutic agents and/or radiation kill cancer cells, an unwanted side effect is the apoptotic death of rapidly dividing non-cancer cells, such as the cells of the gastrointestinal tract, skin, hair and bone marrow cells (page 11, lines 22-25). Weber et al. teach topical or oral administration (reference claim 2) or injection (reference claim 11) and a pharmaceutical composition with an acceptable carrier (reference claim 12). Weber et al. teach the intentional administration due to chemotherapy (reference claim 1). Weber et al. teach the administration of the caspase inhibitor prior, during or after the exposure event (reference claims 17-19). Weber et al. teach various caspase inhibitor compounds (reference claims 13-16) which includes the compound Cbz-Val-Asp-CH_2F (reference claim 14, line 3). Weber et al. teach that skin, hair cells, gastrointestinal tract *inter alia* can be protected via the administration of a caspase inhibitor (page 12, lines 1-3). Weber et al. teach the caspase inhibitor can be administered intraperitoneal (page 36, line 23).

See 35 U.S.C. 103 rejection at 5 *supra* for the rejection of instant claims 1-11 and 14-18.

Weber et al. does not teach a method of treating of ameliorating diseases or conditions caused by the exposure to biological agents such as anthrax.

Park et al. teach that the bacterium Bacillus anthracis induced apoptosis in macrophages (Abstract).

One of ordinary skill in the art at the time of the invention would have known that chemotherapeutic agents, as is the case with Bacillus anthracis as taught by Park et al., is toxic to cells and causes apoptosis.

It would have been obvious to one of ordinary skill in the art at the time of the invention that because it has been shown that the caspase inhibitor Cbz-Val-Asp-CH_2F is capable of treating or ameliorating bone marrow cell death resulting from exposure to a toxic agent such as a chemotherapeutic agent, the caspase inhibitor Cbz-Val-Asp-CH_2F would also be effective at treating or ameliorating apoptosis of other cells subjected to a toxic agent such as anthrax. One of ordinary skill in the art at the time of the invention would have been motivated to utilized the caspase inhibitor due to the similarity between the toxic effects of a chemotherapeutic agent and anthrax and one of ordinary skill in the art would have had a reasonable expectation of success based upon the prior art by Weber et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or

would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937,214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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8. Claims 1, 2 and 17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 6 and 8 of U.S. Patent No. 6,596,693. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claims a method of treating of ameliorating diseases or conditions caused by the exposure to radionuclides, biological agents and chemical

agents wherein the agent, a caspase inhibitor, modulates cell death in response to such exposure. The instant application claims the cell death can occur in the skin, hair, bone marrow, immune system *inter alia*.

Patent '693 teaches the genus encompassing Cbz-Val-Asp-CH_2F in a method of inhibiting cell death of a cell or tissue in reference claims 1 and 2. '693 teaches the cell death is due to a viral infection or radiation induced nerve cell death or the cell death is in the immune system in reference claims 3, 6 and 8.

It would have been obvious to one of ordinary skill in the art at the time of the invention that the use of the exact caspase agent for a viral infection, which would include the viral infections Ebola and Marburg in instant claim 1 will render instant claim 1 obvious. Because '693 teaches the agent treats the immune system, instant claim 2 is rendered obvious. Because '693 teaches the genus of instant claim 17, instant claim 17 is rendered obvious.

No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH S. KUDLA whose telephone number is (571)270-3288. The examiner can normally be reached on 9am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph S. Kudla/
Examiner, Art Unit 1611
September 25, 2008

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611